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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,195	12/03/2003	Carmen V. Pepicelli	HUIP-P02-032	6922

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FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER
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HOWARD, ZACHARY C

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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03/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/727,195

Applicant(s)

PEPICELLI ET AL.

Examiner

Zachary C. Howard

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 06 February 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: 1, 2 and 19-22.  
Claim(s) rejected: 1-4 and 19-26.  
Claim(s) withdrawn from consideration: 5-17.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

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Continuation of 3. NOTE: The claims as examined in the Final Office Action (mailed 8/3/2006) are directed to (1) a method for inhibiting or reducing the proliferation or growth of lung cancer cells comprising contacting the cells with an amount of an agent effective to inhibit or reduce the proliferation or growth of the lung cancer cells, wherein the agent is a ptc therapeutic (claims 1, 3, 4, 5-17, 21, 25 and 26; claims 5-17 are withdrawn as directed to non-elected species) or (2) a method for inducing the formation of, or the maintenance or functional performance of normal lung tissue, comprising contacting lung tissue with an amount of an agent effective to induce the formation of new lung tissue, wherein the agent is a ptc therapeutic (claims 2 and 19-24). In response to the Final Office Action mailed 8/3/2006, Applicants propose amending the claims such that each claim would be directed to a method of screening test compounds to identify either an inhibitor of lung cancer growth or an inducer of formation of normal lung tissue. The proposed amendments to the claims raise new issues that would require further consideration and/or search. First, the consideration with regard to enablement and written description would be considerably different for the proposed amended claims as compared to previously examined claims. The previously examined claims were rejected for lack of enablement and written description with regard to using known compounds as inhibitors or activators of the hedgehog pathway to achieve a desired result related to the growth of lung cancer or normal lung tissue. The claims as amended would require further consideration of whether the specification as filed provides enablement and written description for methods of screening a large genus of test compounds in order to identify specific compounds within this genus that are inhibitors or activators. Furthermore, the claims as amended would require a new search to determine if there is any prior art that anticipates and/or renders obvious methods of screening test compounds to identify modulators of the hedgehog pathway that inhibitors of lung cancer growth or activators of normal lung tissue growth. For these reasons, the proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered.

Continuation of 11. does NOT place the application in condition for allowance because: The request for reconsideration is not persuasive because the arguments are directed to the amended claims which are not entered, and the previous rejections are maintained for the reasons of record.